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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,895	03/19/2004	Madhavan Pisharodi	PISA,015	8181

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3774

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,895	Applicant(s) PISHARODI, MADHAVAN	
	Examiner Paul B. Prebilic	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11 and 19-35 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

The Applicant's response was sufficient to overcome the rejections as they were set forth in the previous Office action. The prior art rejections from the previous Office action have been modified to address the issues raised by the Applicant.

The Applicant failed to at least acknowledge the request for a list of copending applications that set forth similar subject matter from the previous Office action; see the second paragraph in the "Conclusion" section of the previous Office action and the present Office action.

Election/Restrictions

Claims 1, 3, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Claim Objections

Claims 19, 28, and 31-35 are objected to because of the following informalities:

With regard to claims 19, 28, and 32-35, the step of "resisting" is confusing since this is not a manipulative step but rather, a feature provided by the implant structure.

With regard to claim 31, the steps of "maintaining" and "biasing" are confusing because there are not manipulative steps, but rather, features provided by the implant structure.

Regarding claims 31, 33, 34, and 35, the steps of “maintaining”, “resisting”, and “limiting” are all due to physical features of the device and are not manipulative steps. Furthermore, these steps may lack original support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 24, 25, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisharodi (US 5,123,926). Pisharodi anticipates the claim language where the step of removing a portion of a disk as claimed is disclosed on column 2, lines 11-18 of Pisharodi, the elongate implant as claimed is the disk prosthesis (2) of Pisharodi, the insert as claimed is spike (8) of Pisharodi, the inserting step as claimed is disclosed on column 3, lines 32-57, the restraining step as claimed is done by the band (14) of Pisharodi and the resisting rotation step is done by the shape of the implant as being larger on the top and bottom as compared to the sides; see Figure 2.

Regarding claim 24, the spike (8) of Pisharodi must be made of a relatively incompressible material as claimed in order to function as a spike. If the spike (8) collapsed with pressure, it would not function to prevent movement of the disk in the disk space as it is disclosed to so function.

Regarding claim 35, the Applicant is directed to see column 3, lines 55-57.

Claims 19 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Perren et al (US 6,019,793). Perren anticipates the claim language where the inserting step as claimed is met by the inserting step of Perren (see column 3, line 66 to column 4, line 2 and see column 1, line 55 to column 2, line 12), the implant is one of the upper or lower plates (1), the insert as claimed is the other of the upper plate (1) or lower plate (1), and the biasing step as claimed is done by means (4) of Perren. The upper plate (1) or lower plate (2) is movably mounted relative to the rest of the implant in that the means (4) allows relative movement. The nature of shape memory alloys above the transition temperature is to be elastic so it is inherent that the implanted device of Perren has its plates biased elastically away from each other by means (4). Flomenbilt et al (US 5,667,522) is cited to show the inherent nature of shape memory alloys of nickel and titanium as utilized by Perren; see the abstract of Flomenbilt. The implant of Perren is elongate as claimed because the drawings show that the insertion axis is longer than the axis transverse thereto; see Figures 4 and 5. Furthermore, it is noted that by inspection of Figure 5 that the distance from the hole in plate (1) to the edge of the plate (1) is greater along the insertion axis than it is along the axis transverse thereto further indicating an elongate device. Even though the drawings are not disclosed as being drawn to scale, the difference between the holes and the edges is pronounced enough that the structure is clearly present.

With regard to claim 24, the springs as claimed are met by the connecting means (4) of Perren.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,123,926) in view of Steffee (US 5,443,514) or Pisharodi (US 5,653,762). Pisharodi meets the claim language as explained supra but fails to disclose a step of rotating the implant after insertion but does teach rolling the implant into a rectangular shape. However, Steffee (see the abstract and the figures) or Pisharodi ('762) (see the abstract and figures) teaches that it was known to reorient similar implants after insertion so that the vertebra engaging elements are oriented in the proper manner. Therefore, it is the Examiner's position that it would have been obvious to insert and reorient the implant of Pisharodi ('926) for the same reasons that Pisharodi ('726) or Steffee does the same, that is, to enable the use of a smaller incision that produces less trauma to the patient.

Regarding claim 30, compression of the implant is inherent to Pisharodi's ('926) device because have to be assembled into the form of Figure 2 before the bands (14) are placed thereover as in Figure 4. Alternatively, the compression of the insert would have been considered clearly obvious to an ordinary artisan.

Regarding claim 33, the flanges on the spikes (8) limit the movement thereof away from the implant; see Figure 2.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi ('926), Steffee, and Pisharodi ('514) as applied to claims 2 and 28-34 above, and further in view of Muhanna (US 6,936,070). Pisharodi ('926) fails to teach the step of filling the space around an implant with a hydrogel as claimed. However, Muhanna teaches that it was known to fill a space around a similar implant with collagen gel, which is a type of hydrogel; see column 7, lines 3-19. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to fill any space around either of the Pisharodi implant with collagen gel for the same reasons that Muhanna does the same or to aid in the cushioning effect desired.

With regard to claim 21, collagen gel is considered to be a protein polymer or a collagen matrix to the extent that this language can be given patentable weight.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi ('926), Steffee, Pisharodi ('514) and Muhanna (US 6,936,070) as applied to claims 20 and 21 above, and further in view of Haldimann (US 6,428,576). Pisharodi ('926) fails to disclose the use of an adhesive in the implantation method to contact the remaining disk or to seal an opening as claimed. However, Haldimann teaches that it was known to use medical grade adhesives to contact the disk and to seal openings; see Figure 1 and column 4, lines 27-48. Therefore, it is the Examiner's position that it would have been obvious to use the medical grade adhesive of Haldimann to contact the disk and to seal any openings in order to prevent migration of the implant or further herniation of the disk or for the same reasons that Haldimann utilizes the same.

Response to Arguments

Applicant's arguments filed August 24, 2009 have been fully considered but they are not persuasive.

The Applicant argues that the band (14) in Pisharodi ('926) is not an insert as set forth in the present claims. Upon review of the rejection, the Examiner agrees and has changed the rejection to equate the insert with the spike (8) of Pisharodi ('926). The Examiner may have inadvertently identified the insert as element (14) instead of element (8). The rejection has additionally amended to address the Applicant's concerns with regard to claim 24.

The Applicant argues that there is a difference in the Perren device in that the SMA is not a biasing material. The Examiner has added a reference to teach the inherent characteristics of shape memory alloys. The Applicant is invited to review the rejection to better understand the Examiner's position. For this reason, the rejection has been maintained.

The Applicant also argues that Perren fails to disclose an elongate implant device. The Examiner has modified the rejection to point out why the device is inherently elongate based upon inspection of the drawings. The Applicant is respectfully requested to refer to the corresponding rejection under Section 102 for a better understanding of the Examiner's position.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be

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applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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